PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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F3.5.05 wy

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/007215	02.07.2004	03.07.2003

International Patent Classification (IPC) or both national classification and IPC
B32B27/08, B32B27/30, B32B27/32, B32B27/36, A61J1/00

Applicant
B. BRAUN MEDICAL AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2004/007215

10/562368

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document/s (D) is/are referred to in this communication:

D1: EP-A-0 774 348 (BRAUN MELSUNGEN AG)
D2: US-A-5 164 258 (SHIDA MITSUZO ET AL)
D3: EP-A-0 459 357 (MITSUI PETROCHEMICAL IND)
D4: WO 97/37628 A (PHARMACIA & UPJOHN)
D5: Domenico Acierno, Luigi Nicolais; Italia Imballaggio, "Dal processo al prodotto", [June 2000]

1. Novelty

1.1 Document D1, which is considered to represent the most relevant state of the art, discloses sterilisable co-extruded films for wrapping containers for solutions, suspensions, solids or mixtures for parenteral, enteral or stomach tube feeding.
The tube consists of three layers, i.e.
(a) polypropylene homopolymer (homo-PP, outer layer),
(b) ethylene vinylalcohol copolymer (EVOH), in particular a copolymer with an ethylene content of 27-38 mole% and
(c) a single-phase PP homo- or co-polymer (inner layer).
The three layers (a), (b) and (c) have thicknesses of 20-40 μm (a), 15-35 μm (b) and 30-50 μm, respectively; cf. D1, the passages cited in the Search Report, in particular the claims.
The material of inner layer (b) is selected to provide the required oxygen barrier properties. It is clear that the ethylene content of the EVOH copolymer is selected to maintain barrier properties during sterilization at 121 °C (cf. p 2/3, bridging paragraph and p 3/l 11-21 and 37).

1.2 The wording of present claim 1 is not clear, since it does not define the matter for which protection is sought (see hereinafter under item VIII).
It appears from the present application that the EVOH material of the intermediate layer of the claimed films corresponds to the material used in D1 (cf. present claim 5). Since the material of the intermediate layer determines the oxygen transmission rate through the film, it is to be assumed that the films according to D1 and the films of the present

application have the same properties as regards oxygen transmission rates.

However, the films according to present claim 1 allow for desorption of water absorbed in the intermediate layer during sterilization, whereas document D1 is silent as regards such desorption properties. Thus, the claimed films appear to be novel over the disclosure in D1.
The subject-matter of present claims 1-16 therefore appears to meet the requirements of Article 33(2) PCT.

2. Inventive Step

The subject-matter of claims 1 to 16 does appear not involve an inventive step in the sense of Article 33(3) PCT for the following reasons:

2.1 The claimed films differ from the most relevant state of the art (D1) in their desorption properties (see hereinabove under 1.2).
The problem to be solved by the present application may therefore be regarded as to provide multilayer films having a low oxygen transmission rate (i.e. less than 0.7 ml/m^2d) and allowing for improved recovery of the gas barrier properties of the core layer after sterilization.

2.2 Document D2 discloses multi-layered structures including a gas barrier layer. According to D2 retort processes which require steam treatment at 90-135°C cause moisture to permeate through the outer layers of the film and be absorbed by the barrier layer. For materials such as polyamide or EVOH, this moisture absorption by the barrier resin causes the oxygen barrier properties of the barrier layer to drop dramatically and thus to lose a significant portion of its gas barrier function.
Thus, document D2 deals with the same problem as the present application.

In document D2, the problem is solved by selecting a specific material for the outer layers of the films, namely a water permeable material which has a high water vapour transmission rate, e.g. a water vapour transmission rate of above 1 g/m^2d (at T = 37.8°C and a relative humidity of 90%). The applicant's attention is directed to the passages cited in the Search Report, in particular the claims.
Thus, these materials have already been employed for the same purpose in similar films. It would therefore be obvious to the person skilled in the art, namely when the

same result is to be achieved, to apply these layers with corresponding effect in a sterilizable film according to document D1, thereby arriving at a film according to present claim 1.
The subject-matter of claim 1 does therefore not involve an inventive step (Article 33(3) PCT).

2.3 As regards dependent claims 2-6, these claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step.

Concerning claims 2-5, the applicant's attention is directed to document D2 which defines inner and outer layers based on (non-polar) polyolefin materials such as polyethylene or polypropylene (cf. in particular claims 1, 10 and 11 as well as col 6/l 21-24 and 30-34). As regards the preferred EVOH materials used for the gas barrier layer, it is referred to the preferred materials according to document D1, claim 4 and p 3/l 6-10.
As regards present claim 6, it was known in the art (e.g. from document D3) to combine materials such as polypropylene, EVOH and polyethylene terephthalate for retort food packaging materials in view of the low permeability to oxygen of the obtained laminates. Document D3 discloses in particular a 5-layer laminate based on EVOH (i.e. saponified ethylene-vinyl acetate copolymer of an ethylene content of 32 mole%; commercial product sold under the tradename Kuraray Eval EP-F, manufactured by Kuraray Co., Ltd), a polyethylene terephthalate and polypropylene to obtain a structure PET/(tie)/EVOH/(tie)/PP wherein the thickness of each layer (in microns) is 80/50/50/50/80, cf. D3, example 1. The skilled person would therefore regard it as a normal option to use PET as a material for an outer layer in the films described in document D1 and/or D2 in order to provide further sterilizable films.

2.4 As regards films including an additional oxygen absorber (present claims 7-12), the following has to be noted:

The use of oxygen absorbers in packaging films is part of the common general knowledge in the field of parenteral nutrition.
It is e.g. known to use ferrous oxygen absorbers which are capable to withstand sterilization and which may be used either in the form of a sachet containing the absorber or in compounded form being part of the multilayer film. The applicant's attention is directed e.g to documents D4 and D5, cf. the passages cited in the Search

Report, in particular D4/page 14 and D5/para. "Rimozione dell'ossigeno da BP Amoco", both of them disclosing multilayer packaging films including oxygen absobers within a layer of the packaging film.
It is clear from D4, that "the skilled person will have no difficulties in obtaining suitable oxygen absorbers in an appropriate amount when designing a container", since "an estimation of a necessary quality and amount can easily be performed" based on the values of the container (volume of the stored material, nature/oxygen barrier capacity of the surrounding material etc.); cf. D4, p 15/l 6-16.
Thus, combining the teaching of D1/D2 and the common general knowledge in the field of parenteral nutrition, the skilled person searching for a solution to the problem underlying the invention, would arrive at the subject-matter of present claims 7-12 (Article 33(3) PCT).

2.5 The multilayer films according to document D1 are sterilizable. They are used for containers for solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, in particular for protecting the contents of such containers from oxygen.
Thus, vapour sterilized multilayer films and their use for pharma films as claimed in present claims 13 to 16 are also not considered to involve an inventive step in view of the disclosure in D1 (Article 33(3) PCT).

Re Item VIII
Certain observations on the international application

The claims do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not defined.

Claim 1 attempts to define the subject-matter in terms of the result to be achieved, namely the ability to desorb water absorbed in the intermediate layer, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Moreover, neither the claims nor the description appear to specify details concerning a method to determine the ability to desorb water absorbed in the intermediate layer. Thus, the claim is also not clear as regards the definition of the property as such.